IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION

United States of America, *et al.*, *ex rel.* Scarlett Lutz and Kayla Webster, Plaintiffs/Relators, v. Laboratory Corporation of America Holdings, Defendant.	)	C/A No. 9:14-3699-RMG **ORDER AND OPINION**

Before the Court is Defendant Laboratory Corporation of America Holdings' ("LabCorp") motion to exclude the testimony of Relators' expert witness, Michael Petron. (Dkt. No. 334.)[1] Relators responded in opposition and LabCorp replied. (Dkt. Nos. 376, 383.) For the reasons set forth below, LabCorp's motion is granted.

I. Background

This is a *qui tam* action in which the United States of America declined to intervene. Relators allege that LabCorp violated the False Claims Act ("FCA") and Anti-Kickback Statute by providing in-office-phlebotomist ("IOP") blood draw services to doctors whom LabCorp knew referred the blood to Health Diagnostic Laboratory ("HDL") and Singulex, Inc. for testing—in exchange for illegal kickbacks, referred to as process and handling ("P&H") fees—on which HDL and Singulex, Inc. then submitted claims for reimbursement from the Government. Relators also

[1] The Court granted LabCorp's motion to seal portions of its legal memorandum and certain exhibits. (Dkt. No. 338.) LabCorp's filing at Dkt. No. 334 is therefore publicly available with redactions. LabCorp's filing at Dkt. No. 401 is under seal with no redactions, for the Court's use here. This order cites to Dkt. No. 401.

allege that LabCorp submitted its own claims for reimbursement on tests that it was referred by those doctors. (Dkt. No. 50.)

II. Legal Standard

Rule 702 of the Federal Rules of Evidence provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702(a)-(d). "Implicit in the text of Rule 702 is a district court's gatekeeping responsibility 'to ensur[e] that an expert's testimony both rests on a *reliable* foundation and is *relevant* to the task at hand.'" *Nease v. Ford* Motor *Co.*, 848 F.3d 219, 229 (4th Cir. 2017) (emphasis in original) (quoting *Daubert v. Merrell Dow Pharms*., 509 U.S. 579, 597 (1993)).

Relevant testimony, "of course, is evidence that helps 'the trier of fact to understand the evidence or to determine a fact in issue.'" *Nease*, 848 F.3d at 229 (quoting *Daubert*, 509 U.S. at 591). "With respect to reliability, the district court must ensure that the proffered expert opinion is based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods." *Nease*, 848 F.3d at 229 (internal quotation marks omitted). "As the Supreme Court has repeatedly explained, *Daubert v. Merrell Dow Pharmaceuticals, Inc.* [ ] offers district courts several guidepost factors that the court '*may* consider' in assessing an expert's evidentiary reliability to the extent that the factors are relevant to the specific facts of the case at hand." *McKiver v. Murphy-Brown, LLC*, 980 F.3d 937, 959 (4th Cir. 2020) (emphasis in original). The "emphasis on the word 'may' [ ] reflects *Daubert*'s description of the Rule 702 inquiry as 'a flexible one.'" *Kumho Tire Co. v. Carmichael*, 526 U.S.

137, 149 (1999) (quoting *Daubert*, 509 U.S. at 594). Factors that the district court may consider include: (1) "[w]hether a theory or technique . . . can be (and has been) tested"; (2) "whether the theory or technique has been subjected to peer review and publication"; (3) its "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the theory or technique has garnered "general acceptance." *Daubert*, 509 U.S. at 593-94; *accord United States v. Hassan*, 742 F.3d 104, 130 (4th Cir. 2014). "These factors may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his [or her] testimony." *McKiver*, 980 F.3d at 959 (alteration in original) (internal quotation marks omitted). Nor is the *Daubert* list of factors "definitive or exhaustive." *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003). Instead, "the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination." *Kumho Tire Co.*, 526 U.S. at 142. For instance, courts have considered whether experts "developed [their] opinions expressly for the purposes of testifying," *Wehling v. Sandoz Pharms. Corp.*, 162 F.3d 1158 (Table), 1998 WL 546097, at *3 (4th Cir. Aug. 20, 1998) or "though research they have conducted independent of the litigation," *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (on remand). This is because, at bottom, the "objective of [the *Daubert* gatekeeping requirement] . . . is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co.*, 526 U.S. at 152.

This reliability inquiry requires the district court to heed "two guiding, and sometimes competing, principles." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999). "On the one hand, . . . Rule 702 was intended to liberalize the introduction of relevant expert evidence,"

id., and "the trial court's role as a gatekeeper is not intended to serve as a replacement for the adversary system," *United States v. Stanley*, 533 F. App'x 325, 327 (4th Cir. 2013) (citing Fed. R. Evid. 702 advisory committee's note), *cert. denied*, 134 S. Ct. 1002 (2014). Indeed, "[a]s with all other admissible evidence, expert testimony is subject to being tested by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 596)). On the other hand, "[b]ecause expert witnesses have the potential to be both powerful and quite misleading, it is crucial that the district court conduct a careful analysis into the reliability of the expert's proposed opinion." *Fultz*, 591 F. App'x at 227 (internal quotation marks omitted). Thus, "given the potential persuasiveness of expert testimony, proffered evidence that has a greater potential to mislead than to enlighten should be excluded." *Westberry*, 178 F.3d at 261.

For this reason, the proponent of the testimony bears the burden of proving it is reliable by a preponderance of the evidence. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). Proponents "do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of the evidence that their opinions are reliable. . . . The evidentiary requirement of reliability is lower than the merits standard of correctness." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994).

III. Discussion

Relators offer Petron as an expert witness on the following topic:

> [T]o quantify damages suffered by the Centers for Medicare & Medicaid Services' ("CMS") Medicare program ("Medicare Program") resulting from LabCorp's submission of, causing the submission of, and/or participating in a conspiracy to submit, false claims to the Medicare Program from 2010 through 2014 in violation of the federal False Claims Act, 31 U.S.C. § 3729 *et seq*. ("FCA"). Specifically, I was asked to identify the following:

A. Improper and Damaged Medicare Part B claims submitted by and paid to Health Diagnostics Laboratories ("HDL") or Singulex, Inc. ("Singulex") for testing services referred by a physician receiving improper remuneration from HDL or Singulex in the form of draw fees or "processing and handling" ("P&H") fees, for which LabCorp performed the phlebotomy services.

B. Improper and Damaged Medicare Part B claims submitted by and paid to LabCorp for testing services referred to LabCorp by a physician receiving P&H fees from HDL or Singulex and where LabCorp was performing phlebotomy services for the HDL or Singulex testing.

(Dkt. No. 376-3 ¶ 8.) In other words, as Petron's report states:

> For purposes of this engagement, I have been asked to calculate damages based upon improper claims submitted to, and paid by, Medicare Part B for which LabCorp performed phlebotomy services. That is, claims paid by Medicare Part B submitted by HDL or Singulex for testing services referred by a healthcare provider receiving P&H fees and for which LabCorp performed phlebotomy services, and claims paid by Medicare Part B submitted by LabCorp for testing services referred to LabCorp by a provider receiving P&H fees from HDL or Singulex where LabCorp was providing phlebotomy services for the HDL or Singulex testing.

(*Id*. ¶ 27.)

LabCorp argues that Petron's opinions are unreliable because they are based on insufficient facts or data and premised on untested assumptions, some of which were supplied by Relators' counsel. The Court has carefully reviewed the Petron report and its exhibits reflecting the data on which Petron relied to form his opinions. For the following reasons, the Court finds that Relators have failed to carry their burden of demonstrating that Petron's opinions are reliable.

The Court of Appeals for the Fourth Circuit endorses quantifying damages under the FCA as "the amount of money the government paid by reason of the false statement above what it would have paid absent the false statement." *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 922 (4th Cir. 2003); *see also United States ex rel. Drakeford v. Tuomey*, 976 F. Supp. 2d 776, 777-78 (D.S.C. 2013) (noting that the *Harrison* damages standard is "based on a cause of action arising solely under the FCA"). This is because the FCA "attaches liability,

not to the underlying fraudulent activity . . . but to the claim for payment." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999). "This view is consistent with the text of the FCA, which provides for recovery of 'damages which the Government sustains because of the act of' the defendant." *United States ex rel. Harrison*, 352 F.3d at 922 (quoting 31 U.S.C. § 3729(a)). "This approach also furthers an important purpose of the FCA, which is to make the government completely whole." *Id*. (citing *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 551-52 (1943)).

Here, Petron sought to calculate damages based on the premise that LabCorp IOPs were stationed in the offices of physicians taking unlawful kickbacks through inflated P&H fees, and that LabCorp facilitated the HDL/Singulex fraudulent scheme by routinely providing blood draws for these fraudulent tests even though LabCorp knew that the claims being submitted to Medicare by HDL/Singulex were fraudulent. Petron's difficulty in proving damages from this theory of liability began with an inability to definitively identify which physicians receiving unlawful kickbacks had LabCorp IOPs in his or her office during the relevant time period. And LabCorp apparently claimed it did not have this data from the relevant time period of approximately 2010 to 2014.

More specifically, Petron formed his opinions on the damages caused by LabCorp by implementing a multi-step methodology to identify the universe of HDL/Singulex false claims made on testing done on blood that a LabCorp IOP drew for a doctor who received a P&H fee from HDL/Singulex. To do this, Petron purported to identify (i) doctors who received P&H fees from HDL/Singulex, (ii) HLD/Singulex claims made on tests ordered by those doctors, and (iii) timeframes in which it was "more likely than not" that a LabCorp IOP drew the blood for that test. (Dkt. No. 376-3 ¶ 48.) The data that Petron applied to this methodology was provided to him by

Relators' counsel and included data produced by LabCorp in this action, summaries of data compiled by HDL, and summaries of data relied on by the Government in *BlueWave*, 9:14-cv-230-RMG. (Dkt. Nos. 376-3 at 43-59; 376 at 20.) Petron did not collect or review the underlying data, although he testified that "the underlying evidence that LabCorp provided is incomplete, inconsistent, not accurate."[2] (Dkt. No. 401-1 at 7, 30.) For instance, one such summary on which Petron relied was prepared by HDL and purports to list P&H fee payments, but Petron could not state whether he "knew for a fact" that a doctor included in the summary had actually been paid a P&H fee, nor could he state "with any degree of certainty" whether all of the doctors listed had been paid P&H fees. (*Id*. at 3.) By contrast, a LabCorp IOP stationed at one doctor's office testified that while there from July 2012 to 2015 she "did not" draw blood for testing by HDL/Singulex. (Dkt. Nos. 332-6 at 6-7; 376-3 at 43-44, 49-50.)

In an effort to create a pool of doctors who received improper P&H fees and had LabCorp IOPs operating in their offices, Petron drew upon four sets of data (J-Codes, draw fee counts, specimen collection agreements, and venipuncture claims of LabCorp), none of which specifically tied a LabCorp IOP draw to a particular HDL/Singulex fraudulent claim. For instance, Petron sought to infer the presence of a LabCorp IOP in a physician's office where LabCorp's J-Code system (reflecting the location where specimens were drawn) exceeded 52 per year or one per week. (Dkt. No. 376-3 at 25-26.)[3] Another data set involved use of Medicare venipuncture claims of LabCorp submitted to Medicare. If the physician in question had at least 260 claims (approximately one per business day for one year), Petron assumed that a LabCorp IOP was in the

[2] Petron testified that the "incomplete, inconsistent, not accurate" characteristics of LabCorp's data supports finding that his damages thresholds are reasonable. (Dkt. No. 401-1 at 30.)

[3] Petron testified that he had "not seen J-Codes but for this case" in response to being asked whether he had "ever seen J-Code counts used in any peer-reviewed materials." (Dkt. No. 401-1 at 14.)

physician's office. (*Id.* at 30-31.) And Petron's use of the 52 and 260 thresholds was not the product of any application of professional expertise or skill; these thresholds were supplied to Petron by Relators' counsel.[4] (Dkt. No. 401-1 at 17-18.)

If a physician in question met the threshold for any one of the four data sets, Petron assumed a LabCorp IOP was present in the physician's office. (Dkt. No. 401-1 at 16-17.) Petron admits, however, that he undertook no independent validation method to test his thresholds or data sets.[5] LabCorp, over the vigorous objections of Relators, took the depositions of 21 physicians identified by Petron as receiving kickbacks to determine if they actually had LabCorp IOPs in their offices during the relevant time period. These depositions revealed that some of the physicians in question had LabCorp IOPs during the relevant time period and some did not. In short, Petron's method of identifying which physician offices had IOPs present during the relevant time period lacked adequate reliable data, was untested, and conflicted with other record evidence. In fact, Petron justified his methods as necessary because of the lack of reliable data:

> Q: So is it your testimony that you don't know who did the draws on any given test, you're just assuming that LabCorp is somehow responsible for all of them in order . . . to meet one of the threshold analyses?
>
> A: There is not data provided to me by LabCorp that allows me to know in specificity exactly who drew what and when exactly. That's why we have the thresholds.

(Dkt. No. 401-1 at 22.)

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[4] LabCorp notes that if a physician's office had only one order per day or one per week (the 260 and 52 thresholds), it would have been insufficient volume to support the placement of an IOP. LabCorp stated it required 20 to 35 orders per day to justify placing an IOP in a physician's office. (Dkt. No. 401 at 18.)

[5] When questioned about whether it is "common, this threshold assumption where you've used these four different categories to include practices," Petron testified that "In - - in situations where I am lacking sufficient detailed data to tie things exactly out, as I believe you would like, this is a very common practice in my field, yes"; although, Petron could not identify other industry standards or practitioners implementing this method. (Dkt. No. 401-1 at 17.)

At another step in Petron's multi-part damages calculation, he sought to determine how many false claims were submitted to Medicare based on LabCorp's alleged complicity with HDL/Singulex by having its IOPs draw the blood for these fraudulent claims. Here, again, Petron was stymied by the lack of data identifying who actually drew the blood for the fraudulently submitted HDL/Singulex claims. While it was possible that a LabCorp IOP did the draw, it was also possible that the blood was drawn by one of the physician's own staff members or by a lab outside the office. Lacking any direct evidence of who actually drew the blood on the questionable claims, Petron declared that it was "more likely than not" that any HDL/Singulex orders in physician offices in question were actually drawn by a LabCorp IOP. (Dkt. No. 376-3 at 32-35.) In other words, Petron assumed that 100% of the HDL/Singulex fraudulent orders in offices with a LabCorp IOP were drawn by the IOP. (Dkt. No. 401-1 at 21.)

LabCorp challenged this assumption and took the depositions of 21 physicians included in Petron's damage calculations to determine the actual practices in their individual offices. These depositions revealed that, among the offices of those 21 physicians, there was no uniform practice. Some physicians denied ever having a LabCorp IOP in the office, others stated they had an IOP but their staff drew the blood on the HDL/Singulex orders, while still others testified that they drew blood for the HDL/LabCorp as a courtesy for their patients. (Dkt. No. 328.) Petron admitted he made no independent effort to validate his assumption of 100% use of LabCorp IOPs to perform HDL/Singulex blood draws and was instructed by Plaintiffs' counsel to assume that every HDL/Singulex test ordered in a physician's office with a LabCorp IOP had the blood drawn for that test by the IOP. (Dkt. No. 401-1 at 28.)

Relators argue that Petron's methods were rendered necessary because LabCorp did not maintain adequate records that could now be used to determine which of the fraudulent

HDL/Singulex orders were actually drawn by a LabCorp IOP. Relators point to a LabCorp corporate handbook that required retention of log books on all IOP draws. LabCorp has responded that such log books were not maintained at the time and do not exist. Petron is not the first damages expert confronted with inconclusive and incomplete data. A party seeking to establish damages with inadequate data can undertake independent inquiries to prove or disprove assumptions and to establish certain practices and actions through sampling techniques. *See, e.g., United States v. DiMartino,* 949 F.3d 67, 74 (2d Cir. 2020) (district court did not abuse its discretion by finding expert's opinion was unreliable, as not based on sufficient facts or data under Rule 702(b), where expert "fail[ed] to seek collateral support for [the party's] assertions"). For instance, to establish whether Petron's formula for identifying which physician offices actually had Lab Corp IOPs present, Relators could have deposed a number of the targeted doctors and obtained the names of their staff members and IOPs who were in the office during the relevant time period. To validate their assumptions about whether LabCorp IOPs were routinely drawing blood for all or some HDL/Singulex orders, Relators could have asked the physicians, staff members and IOPs about the practices in their offices.

The bottom line is that the burden of proof is on the party offering expert testimony to demonstrate that the opinions presented are based on reliable data, the expert is utilizing reliable principles, and methods and the principles are reliably applied. Petron's testimony is undermined by the absence of reliable data and the reliance on assumptions provided by Relators' counsel rather than as a result of the application of professional expertise. When Petron's questionable assumptions and methods are combined in a multi-step formula, the result simply lacks any semblance of reliability.

In addition to the lack of reliable data and methods, Petron's opinions have the potential to be quite misleading to the jury. Relators argue that LabCorp was complicit with HDL/Singulex and routinely and knowingly performed blood draws on these unlawful orders. LabCorp acknowledges that some of its IOPs, as a courtesy to patients, would make blood draws for the HDL/Singulex orders at the same time blood draws were being made for LabCorp orders. The extent of Lab Corps blood draws for HDL/Singulex orders will obviously be contested at trial, but for the reasons discussed, the record evidence here does not support the Petron damage calculations that assumes 100% of the HDL/Singulex orders were performed by LabCorp IOPs situated in the offices of the physicians receiving P&H payments.

The FCA offers no guidance as to how damages should be measured other than to explicitly provide that one who violates the Act is liable for damages "substain[ed] because of the act of that person." 31 U.S.C. § 3729(a)(1). At bottom, the question is whether Relators carried their burden of demonstrating that the Government sustained damages "because of" LabCorp IOPs drawing blood that was referred to HDL/Singulex for testing by doctors whom LabCorp knew were receiving P&H fee kickbacks. Petron's opinion is predicated on a series of assumptions purporting to identify whether a LabCorp IOP was both in a doctor's office and drew blood that was tested by HDL/Singulex. "An expert's opinion should be excluded when it is based on assumptions which are speculative and are not supported by the record." *Tyger Const. Co. inc. v. Pensacola Const. Co.*, 29 F.3d 137, 142 (4th Cir. 1994). Petron then sought to prove-up these speculative assumptions with data that itself are unverified or contradicted by the record evidence. The Court may exclude an expert's opinion if "there is simply too great an analytical gap between the data and the opinion offered." *EEOC v. Freeman*, 778 F.3d 463, 472 (4th Cir. 2015). Compounded, these speculative assumptions and unverified facts produce an opinion that poses a greater risk of

confusing or misleading the jury than aiding it. For these reasons, the Court finds that Relators have failed to carry their burden of demonstrating that Petron's opinion is reliable by a preponderance of the evidence under the standards contemplated by Rule 702.

IV. Conclusion

For the foregoing reasons, LabCorp's motion to exclude the testimony of Relators' expert witness on damages, Michael Petron, (Dkt. No. 334) is **GRANTED**.

AND IT IS SO ORDERED.

s/ Richard Mark Gergel
Richard Mark Gergel
United States District Judge

July 6, 2021
Charleston, South Carolina